

REMARKS

Applicant appreciates the time taken by the Examiner to review Applicant's present application. This application has been carefully reviewed in light of the Official Action mailed on July 22, 2008 ("Office Action"). Claims 1-14, 21-22, and 30 have been withdrawn from consideration. Claims 15-20 and 29 were canceled previously. Claims 23-28 and 31-53 were pending and rejected. Claims 23, 26-27, 31, 33, 36-38, 40, 44-45, 47, and 52 are amended herein. No claim is newly added. As a good faith effort to forward prosecution, independent claims 23, 33, 40, and 47 are amended herein to recite, among others, "preparing an opening in a bone using a bone tap." Support for the amendments to the claims presented herein can be found in the Specification as originally filed, at least from page 5, lines 11-12. No new matter is introduced. Thus, claims 23-28 and 31-53 remain pending in the application. Applicant respectfully requests reconsideration and favorable action in this case.

Rejections under 35 U.S.C. § 102

Claims 23, 24, 26, and 27 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,752,809 ("Gorek"). Additionally, Claims 23, 24, 26, and 27 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,610,079 ("Li").

Applicant respectfully traverses these rejections. Arguments submitted in the previous reply filed on April 25, 2008 remain pertinent to the rejections and are therefore incorporated herein by reference.

It is respectfully noted that multiple references were used against claims 23, 24, 26, and 27. Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. *See* M.P.E.P. 2131.01.

Applicant respectfully maintains that neither Gorek nor Li anticipates Claims 23, 24, 26, and 27. Although itself has no force of law, the M.P.E.P. restates the following law: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, for both Gorek and Li to anticipate claims 23, 24, 26, and 27, Gorek must teach every element of claims 23, 24, 26, and 27 and Li must teach every element of claims 23, 24, 26, and 27. *See* M.P.E.P. 2131.

According to M.P.E.P. 706.02 (V),

“the distinction between rejections based on 35 U.S.C. § 102 and those based on 35 U.S.C. § 103 should be kept in mind. Under the former, the claim is anticipated by the reference. No question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. Whereas, in a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made. See MPEP § 2131 - § 2146 for guidance on patentability determinations under 35 U.S.C. 102 and 103.”

Thus, for Gorek to anticipate claims 23, 24, 26, and 27, there must be no question of obviousness present, Gorek must teach every aspect of claims 23, 24, 26, and 27 either explicitly or impliedly, and any feature not directly taught must be inherently present in Gorek. It is respectfully submitted that Gorek does not anticipate claims 23, 24, 26, and 27 at least because the threaded cannula 100 of Gorek is not a bone tap as set forth in claims 23, 24, 26, and 27. It is respectfully submitted that it is questionable whether, at the time the invention was made, one of ordinary skill in the art would have interpreted the threaded cannula 100 of Gorek as a bone tap. Gorek does not appear to, expressly or implicitly, describe that the threaded cannula 100 is a bone tap. If this ground of rejection is to be maintained in the next Office Action, it is respectfully requested that the examiner provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of Gorek.

According to M.P.E.P. 2112 (IV),

"To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference

"discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species).

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Applicant respectfully disagrees with the examiner's statement on page 6 of the Office Action that "Gorek discloses all elements of Applicant's claimed invention." It is respectfully submitted that Gorek does not at all disclose all the elements contained in claims 23, 24, 26, and 27. The cannula 100 of Gorek do not anticipate a bone tap as Gorek explicitly describes using the applicator 118 to assist the surgeon in threading the cannula 100 into a tapped drill hole. *See* Gorek, col. 6, lines 21-24. That is, Gorek specifically distinguishes the cannula 100 from a bone tap. Moreover, the applicator 118 of Gorek does not anticipate a driver as Gorek explicitly describes that the applicator 118 is used to provide structural support for the cannula 100 from inside the cannula 100. *Id.* Gorek does not explicitly or implicitly describe using the applicator 118 to drive the cannula 100 into the tapped drill hole.

It is respectfully submitted that claims 23, 24, 26, and 27 recite subject matter not reached by Gorek not only under 35 U.S.C. § 102(e), but also under 35 U.S.C. § 103(a). In embodiments as claimed in claims 23, 24, 26, and 27, a fluid can be introduced through a bone tap into a bone without the cannula

100 and the applicator 118 of Gorek. According to M.P.E.P. 2144.04 (II)(B), omission of an element with retention of the element's function is an indicia of unobviousness:

Note that the omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966) (Claims at issue were directed to a printed sheet having a thin layer of erasable metal bonded directly to the sheet wherein said thin layer obscured the original print until removal by erasure. The prior art disclosed a similar printed sheet which further comprised an intermediate transparent and erasure-proof protecting layer which prevented erasure of the printing when the top layer was erased. The claims were found unobvious over the prior art because the although the transparent layer of the prior art was eliminated, the function of the transparent layer was retained since appellant's metal layer could be erased without erasing the printed indicia.).

In view of the foregoing, it is respectfully submitted that claims 23, 24, 26, and 27 are patentable over Gorek under 35 U.S.C. §§ 102 and 103 and therefore should be allowed.

For Li to anticipate claims 23, 24, 26, and 27, there must be no question of obviousness present, Li must teach every aspect of claims 23, 24, 26, and 27 either explicitly or impliedly, and any feature not directly taught must be inherently present in Li. It is respectfully submitted that Li does not anticipate claims 23, 24, 26, and 27 at least because the fastener 70 of Li is not a bone tap as set forth in claims 23, 24, 26, and 27. It is respectfully submitted that it is questionable whether, at the time the invention was made, one of ordinary skill in the art would have interpreted the fastener 70 of Li as a bone tap. Li does not appear to, expressly or implicitly, describe that the fastener 70 is a bone tap. If this ground of rejection is to be maintained in the next Office Action, it is respectfully requested that the examiner provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of Li.

Furthermore, claims 23, 24, 26, and 27 recite, among others, a bone fastener. A suture is not a bone fastener. If this ground of rejection is to be maintained in the next Office Action, it is respectfully requested that the examiner provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic (i.e., a suture anticipating a bone fastener) necessarily flows from the teachings of Li.

It is respectfully submitted that claims 23, 24, 26, and 27 recite subject matter not reached by Li not only under 35 U.S.C. § 102(e), but also under 35 U.S.C. § 103(a). In embodiments as claimed in

claims 23, 24, 26, and 27, a fluid can be introduced into a bone through a bone tap. This has many advantages. For example, embodiments as claimed in claims 23, 24, 26, and 27 can allow the fluid introduced into the bone through the bone tap to harden prior to introducing a bone fastener. As another example, embodiments as claimed in claims 23, 24, 26, and 27 can allow controlled delivery of the fluid to multiple locations. If the fluid is needed in more than one location, embodiments as claimed in claims 23, 24, 26, and 27 can allow the fluid be introduced to another location via the same bone tap. In contrast, since a bone fastener is fastened into a bone at a fixed location, Li appears to rely on the fact that the polymer being injected into is flowable.

In view of the foregoing, it is respectfully submitted that claims 23, 24, 26, and 27 are patentable over Li under 35 U.S.C. §§ 102 and 103 and therefore should be allowed.

Claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,622,731 ("Daniel"). Applicant respectfully traverses these rejections. Arguments submitted in the previous reply filed on April 25, 2008 remain pertinent to the rejections and are therefore incorporated herein by reference.

For Daniel to anticipate claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53, there must be no question of obviousness present, Daniel must teach every aspect of claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53 either explicitly or impliedly, and any feature not directly taught must be inherently present in Daniel. It is respectfully submitted that Daniel does not anticipate claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53 at least because Daniel does not disclose a bone tap having openings through which a fluid is introduced to a bone as set forth in claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53. Daniel does disclose that the introducer 292 can include or otherwise be configured as a bone access or insertion device. *See* Daniel, col. 22, lines 3-6. However, Daniel does not explicitly describe that the introducer 292 is a bone tap having openings through which a fluid is introduced into a bone. Thus, it is questionable whether, at the time the invention was made, one of ordinary skill in the art would have interpreted Daniel as anticipating exactly as set forth in claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53. If this ground of rejection is to be maintained in the next Office Action, it is respectfully requested that the examiner provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of Daniel.

Applicant respectfully disagrees with the examiner's statement on page 7 of the Office Action that "Daniel discloses all elements of Applicant's claimed invention." It is respectfully submitted that

Daniel does not at all disclose all the elements contained in claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53. For example, as submitted in the previous reply filed on April 25, 2008, in Daniel, a fluid is not introduced through openings of a bone tap. Rather, the fluid is introduced through apertures in an electrode extending from the introducer 292.

In view of the foregoing, it is respectfully submitted that claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53 recite subject matter not reached by Daniel under 35 U.S.C. § 102(e) and therefore should be allowed.

Rejections under 35 U.S.C. § 103

Claim 25 was rejected under 35 U.S.C. §103(a) as being unpatentable over Gorek in view of U.S. Patent No. 6,599,293 ("Tague"). Additionally, claim 25 was rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of U.S. Patent No. 6,599,293 ("Tague"). Claim 25 depends from claim 23. As submitted above, claim 23 recites subject matter not reached by Gorek or Li under 35 U.S.C. § 103. Accordingly, reliance is placed on *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) for the allowance of claim 25.

Claims 28, 31, and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gorek. Claims 28, 31, and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Li. Claims 28, 31, and 32 depend from claim 23. As submitted above, claim 23 recites subject matter not reached by Gorek or Li under 35 U.S.C. § 103. Accordingly, reliance is placed on *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) for the allowance of claims 28, 31, and 32.

Claims 35, 43 and 50 were rejected under 35 U.S.C. §103(a) as being unpatentable over Daniel in view of Tague. Claims 39, 41 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Daniel. Claims 35 and 39 depend from claim 33. Claims 41 and 43 depend from claim 40. Claims 48 and 50 depend from claim 47. Claims 40 and 47 contain elements similar to those recited in claim 33. Thus, traversal to the rejections will be collectively discussed below with respect to claim 33.

Claim 33 recites a method of introducing a fluid into a bone, comprising:

- preparing an opening in a bone using a bone tap, the bone tap comprising a body, a passage, one or more openings communicating with the passage, and threading located near an end of the body of the bone tap;
- introducing a fluid to the bone through at least one of the openings of the bone tap;

allowing the fluid to spread to a portion of the bone;
and
coupling a removable driver to the bone tap, and
using the driver to remove the bone tap from the bone.

Claim 33 includes preparing an opening in a bone using a bone tap and introducing a fluid to the bone through at least one of openings in the bone tap. Thus, a bone tap used to prepare an opening for insertion of a subsequent bone fastener can also be used to introduce a fluid into the bone.

Contrastingly, Daniel teaches a system of delivering an electrode to a tumor to ablate the tumor. *See* Daniel col. 2, lines 1-6. An introducer is used to pass through bone to reach the tumor and then an electrode is extended from the introducer for deployment into the tumor. *See* Daniel col. 17, lines 59-col. 19, line 28. The electrode can include apertures through which conductive viscoelastic gel can be introduced to the tumor.

In contrast to embodiments as claimed in claims 33, 40 and 47, the introducer of Daniel is not a bone tap as it is not used to prepare an opening for a fastener. The threaded section of the introducer can be self tapping to allow a surgeon to screw in the introducer through harder bone to reach a tumor but it is not used as a bone tap to tap an opening for a subsequent bone fastener. As a further distinction, the fluid of Daniel is not introduced through openings in the introducer, but is, instead, introduced through apertures in an electrode extending from the introducer. *See* FIGURES 18B and 19B of Daniel.

Furthermore, the fluid of Daniel does not appear to cure into a hard substance. Instead, it is a viscoelastic conductive gel or paste that stays within the bone during ablation to uniformly deliver electromagnetic energy. The viscoelastic gel does not appear to harden as does cement. *See* United States Patent No. 4,299,231 (cited in Daniel), col. 2, lines 10-21, describing viscoelastic gels.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Accordingly, it is respectfully submitted that claims 35, 39, 41, 43, 48 and 50 recite subject matter not reached by Daniel and Tague, individually and in combination, under 35 U.S.C. §103(a) and therefore should be allowed.

CONCLUSION

Applicant has now made an earnest attempt to place this case in a condition for allowance. Other than as explicitly set forth above, this reply does not include any acquiescence to statements, assertions, assumptions, conclusions, or any combination thereof in the Office Action. For the foregoing reasons and for other reasons clearly apparent, Applicant respectfully requests favorable reconsideration and full allowance of the pending claims 23-28 and 31-53.

The Examiner is invited to contact the undersigned at the phone number indicated below with any questions or comments, or to otherwise facilitate expeditious and compact prosecution of the application.

Respectfully submitted,
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